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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/609,027	06/29/2000	Wayne A. Hendrickson	50950/JPW/EMW	1817

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EXAMINER

ZHOU, SHUBO

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 03/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/609,027

Applicant(s)

HENDRICKSON ET AL.

Examiner

Shubo "Joe" Zhou

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,22,26,27 and 48-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,22,26,27 and 48-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment and request for reconsideration in Paper #17, filed on 10/25/02, is acknowledged and the amendments entered.

Applicant's arguments in response to the previous Office Action, mailed 5/21/02, have been fully considered. Rejections and/or objections from previous Office actions not reiterated herein are hereby withdrawn. The following rejections and/or objections are either reiterated from the previous Office actions, or newly applied, and constitute the complete set presently being applied to the instant application.

Claims 21-22, 26-27, and 48-51 are currently pending and under consideration.

Claim Rejections-35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-22, 26-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of designing a compound binding to kit using the coordinates of SCF fragment crystal consisting of the sequence of SEQ ID NO:1, does not reasonably provide enablement for a method using the coordinates of any SCF fragment or any polypeptide comprising the sequence of SEQ ID NO:1. The specification does not enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

This rejection is reiterated from the previous Office action and maintained for reasons of record. While the present rejection is a scope of enablement rejection, it is set forth in the previous Office action. See page 4.

The claims require making crystals and determining the 3-D structure of any fragment of a SCF protein. Applicants argue that since the specification provide example for the fragment of SCF comprising SEQ ID NO:1, those skilled in the art would know how to make crystals of any fragment of SCF for X-ray crystallography is routine, uses extensive automation and has been an established field for more than 50 years. This is not deemed persuasive because, as set forth in the previous Office action, the field of crystallography is unpredictable, and as such, the specification, which lacks guidelines to make crystals of any SCF fragment, is not enabling for using each and every crystal structure of the portion/fragment of SCF polypeptide. While there are kits or automation system for crystallography commercially available, it is well established in the field that ~~the~~ although utilization of a variety of crystallization methods including kits, for the protein in question, greatly improves the chances of identifying suitable conditions for crystallization, obtaining suitable single crystal(s) is the least understood step in the X-ray structural analysis of a protein(s). Therefore, since the science of protein crystallization is underdeveloped, the crystallization of a protein is mainly a trial-and-error procedure. See, for example, Jan Drenth ("Principles of Protein X-ray Crystallography", pages 1-9). Note that the Drenth reference is provided to support the notion set forth in the previous Office action that protein crystallography is unpredictable.

Newly added claims 48-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of designing a compound binding to kit using the coordinates of SCF fragment crystal comprising the sequence of SEQ ID NO:1, does not reasonably provide enablement for a method using the coordinates of any SCF fragment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 48-51 are rejected for the same reasons as set forth for the rejection of claims 21-22, 26-27 as set forth in the previous Office action and above.

Claim Rejections-35 USC § 112, Second Paragraph

Claims 21-22, 26-27, and 48-51 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “the 3-D structure shape complementarity or estimated interaction energy” in claims 48 lacks clear antecedent basis. “3-D structure shape complementarity or estimated interaction energy” is nowhere cited earlier in the claim. Claims 21-22, 26-27, and 49-51 are rejected due to their dependency from claim 48.

Claim Rejections-35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mohammadi et al. (WO 98/07835, 2/26/1998).

The claims are drawn to a method of performing a computer analysis of using the structural coordinates to identify an agent that potentially binds to Kit protein.

In addition to disclosing making a crystal and determine the structure of a protein tyrosine kinase, Mohammadi et al. shows in the abstract and throughout a method of performing a computer analysis of using the structural coordinates of the protein kinase to identify an agent that binds to and modulate the protein tyrosine kinase. See the abstract, lines 10-17 of page 4. Such a modulator can activate or inhibit the catalytic activity of the protein tyrosine kinase. See page 11, lines 5-25. Mohammadi et al. also disclose that these modulators are identified by docking a computer representation of a structure of a protein tyrosine kinase with or without a compound binding to, which structure is defined by structural coordinates. See pages 29-35.

The computational process of identifying modulators by Mohammadi et al. differs from the claimed invention only in the content of the crystal coordinates. The MPEP states in 2106 section VI in discussing computer related inventions in light of *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983):

***VI. DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES
WITH 35 U.S.C. 102 AND 103***

*As is the case for inventions in any field of technology, assessment of a claimed computer-related invention for compliance with 35 U.S.C. 102 and 103 begins with a comparison of the claimed subject matter to what is known in the prior art. If no differences are found between the claimed invention and the prior art, the claimed invention lacks novelty and is to be rejected by Office personnel under 35 U.S.C. 102. Once distinctions are identified between the claimed invention and the prior art, those distinctions must be assessed and resolved in light of the knowledge possessed by a person of ordinary skill in the art. Against this backdrop, one must determine whether the invention would have been obvious at the time the invention was made. If not, the claimed invention satisfies 35 U.S.C. 103. Factors and considerations dictated by law governing 35 U.S.C. 103 apply without modification to computer-related inventions. If the difference between the prior art and the claimed invention is limited to descriptive material stored on or employed by a machine, Office personnel must determine whether the descriptive material is functional descriptive material or nonfunctional descriptive material, as described supra in sections IV.B.1(a) and IV. B.1(b). Functional descriptive material is a limitation in the claim and must be considered and addressed in assessing patentability under 35 U.S.C. 103. Thus, a rejection of the claim as a whole under 35 U.S.C. 103 is inappropriate unless the functional descriptive material would have been suggested by the prior art. > *In re Dembiczak*,*

175 F.3d 994, 1000, 50 USPQ2d 1614, 1618 (Fed. Cir. 1999).< Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. Cf. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).

Common situations involving nonfunctional descriptive material are:

- a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium,*
- a computer that differs from the prior art solely with respect to nonfunctional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer),*
- or*
- a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.*

Thus, if the prior art suggests storing a song on a disk, merely choosing a particular song to store on the disk would be presumed to be well within the level of ordinary skill in the art at the time the invention was made. The difference between the prior art and the claimed invention is simply a rearrangement of nonfunctional descriptive material.

The difference between Mohammadi et al. and the claimed invention constitutes non-functional descriptive material because the content of the structure coordinates of a protein or protein complex does not alter how the computational method functions, i.e., the structural coordinates of the protein does not limit the claimed method to perform different steps than the method of Mohammadi et al. Therefore no patentable weight is given to the structural coordinates of the protein in the claimed method.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

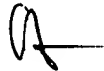
Any inquiry concerning this communication or earlier communications from the examiner should be directed to:
Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

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Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is (703)-305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou, Ph.D.



Patent Examiner



MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600